

Form PTO-1449 (modified)

Atty. Docket No.  
ARCD:389USSerial No.  
10/751,606

List of Patents and Publications for Applicant's

Applicant  
Mark Ratain *et al.*

INFORMATION DISCLOSURE STATEMENT

Filing Date:  
January 5, 2004Group:  
1645

(Use several sheets if necessary)

U.S. Patent Documents  
See Page 1Foreign Patent Documents  
See Page 1Other Art  
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## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
SB	A9	2002/0061518	5/28/02	Penny and Galvin	435	6	5/05/99
	A10	2003/0077629	4/24/03	Galvin <i>et al.</i>	435	6	7/24/02
	A11	2003/0099960	5/29/03	Ratain <i>et al.</i>	435	6	1/25/02
	A12	2003/0099977	5/29/03	Guida and Kurth	435	6	7/26/02
	A13	2003/0157517	8/21/03	Penny and Galvin	435	6	9/18/02
	A14	2004/0058363	3/25/04	Hasegawa <i>et al.</i>	435	6	6/12/03
	A15	2004/0076968	4/22/04	Acuna <i>et al.</i>	435	6	7/02/01
	A16	2004/0121327	6/24/04	Manns and Strassburg	435	6	1/03/02
	A17	2004/0203034	10/14/04	Ratain <i>et al.</i>	435	6	1/05/04
	A18	5,972,614	10/1999	Ruano <i>et al.</i>	436	6	
	A19	6,448,003	9/10/2	Guida and Kurth	435	6	6/08/99
SB	A20	6,586,175	7/01/03	Galvin <i>et al.</i>	435	6	7/20/99

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
SB	B6	JP 2004-073035	3/11/04	Japan			Abstract
	B7	EP 1352970	10/15/03	Europe			English
	B8	WO 01/79230	10/25/01	WIPO			English
	B9	WO 02/053770	7/11/02	WIPO			English
	B10	WO 02/057410	7/25/02	WIPO			English
	B11	WO 02/06523	1/24/02	WIPO			English
	B12	WO 2003/013536	2/20/03	WIPO			English
SB	B13	WO 2003/013537	2/20/03	WIPO			English

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### Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
SB	B14	WO 2004/016814	2/26/04	WIPO			Abstract
SB	B15	WO 97/32042	9/04/97	WIPO			English
SB	B16	WO 99/57322	11/11/99	WIPO			English

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
SB	C218	Ando <i>et al.</i> , "UGT1A1 genotypes and glucuronidation of SN-38, the active metabolite of irinotecan," <i>Annals of Oncology</i> , 9:845-847, 1998.
SB	C219	Beutler <i>et al.</i> , "Racial variability in the UDP-glucuronosyltransferase 1(UGT1A1) promoter: a balanced polymorphism for regulation of bilirubin metabolism," <i>Proc. Natl. Acad. Sci., USA</i> , 95:8170-8174, 1998.
SB	C220	Clarke <i>et al.</i> , "Genetic defects of the UDP-glucuronosyltransferase-1 (UGT1) gene that cause familial non-hemolytic unconjugated hyperbilirubinemias," <i>Clinica Chimica Acta</i> , 266:63-74, 1997.
SB	C221	De Morais <i>et al.</i> , "Decreased glucuronidation and increased bioactivation of Acetaminophen in Gilbert's syndrome," <i>Gastroenterology</i> , 102:577-586, 1992.

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SB	A1	5,786,344	7/28/98	Ratain <i>et al.</i>	514	100	4/17/95
	A2	6,066,645	5/23/00	Hausheer <i>et al.</i>	514	283	1/6/99
	A3	6,287,834	9/11/01	Belanger <i>et al.</i>	435	193	2/08/99
	A4	6,319,678	11/20/01	Trubetskoy and Shaw	435	15	6/25/99
	A5	6,395,481	5/28/02	Di Rienzo <i>et al.</i>	435	6	1/16/99
	A6	6,407,117	6/18/02	Bouscarel <i>et al.</i>	514	283	3/23/00
	A7	6,472,157	10/29/02	De Rienzo and Ratain	435	6	2/01/02
	A8	6,479,236	11/12/02	Penny and Galvin	435	6	5/05/99

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Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
SB	B1	EP 0919244	6/2/99	Europe			Abstract
SB	B2	WO 00/06776	2/10/00	PCT			
SB	B3	WO 94/22846	10/94	PCT			
SB	B4	WO 95/08986	4/6/95	PCT			
SB	B5	WO 96/01127	1/18/96	PCT			

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
SB	C1	Abraham <i>et al.</i> , "Non-glucocorticoid steroid analogues (21-aminosteroids) sensitize multidrug resistant cells to vinblastine," <i>Cancer Chemother. Pharmacol.</i> , 32(2):116-122, 1993.
SB	C2	Akiyama <i>et al.</i> , "Most drugs that reverse multidrug resistance also inhibit photoaffinity labeling of p-glycoprotein by a vinblastine analog," <i>Mol. Pharmacol.</i> , 33(2):144-147, 1988.

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Exam. Init.	Ref. Des.	Citation
SB	C3 ✓	Ando <i>et al.</i> , "Polymorphisms of UDP-glucuronosyltransferase gene and irinotecan toxicity: a pharmacogenetic analysis," <i>Cancer Res.</i> , 60(24):6921-6926, 2000.
	C4 ✓	Ansher <i>et al.</i> , "Chemoprotective effects of two dithiolthiones and of butylhydroxyanisole against carbon tetrachloride and acetaminophen toxicity," <i>Hepatology</i> , 3(6):932-935, 1983.
	C5 ✓	Araki <i>et al.</i> , "Relationship between development of diarrhea and the concentration of SN-38, an active metabolite of CPT-11, in the intestine and blood plasma of athymic mice following intraperitoneal administration of CPT-11," <i>Jpn. J. Cancer Res.</i> , 84:697-702, 1993.
	C6 ✓	Ariyoshi <i>et al.</i> , "Mouse-human chimeric antibody MH171 against the multidrug transporter P-glycoprotein," <i>Jpn. J. Cancer Res.</i> , 83(5):515-521, 1992.
	C7 ✓	Atsumi <i>et al.</i> , "Identification of the Metabolites of Irinotecan, a New Derivative of Camptothecin, in Rat Bile and its Biliary Excretion," <i>Xenobiotica</i> , 21(9):1159-1169, 1991.
	C8 ✓	Barbier <i>et al.</i> , "3'-azido-3'-deoxythymidine (AZT) is glucuronidated by human UDP-glucuronosyltransferase 3B7 (UGT2B7)," <i>Drug Metab. Dispos.</i> , 28:497-502, 2000.
	C9 ✓	Barker <i>et al.</i> , "Determination of plasma concentrations of epirubicin and its metabolites by high-performance liquid chromatography during a 96-h infusion in cancer chemotherapy," <i>J Chromatogr B Biomed Appl</i> , 681:323-329, 1996.
	C10 ✓	Bear, "Drugs transported by P-glycoprotein inhibit a 40pS outwardly rectifying chloride channel," <i>Biochem. Biophys. Res. Commun.</i> , 200(1):513-521, 1994.
	C11 ✓	Bell <i>et al.</i> , "Roles of peptidyl-prolyl cis-trans isomerase and calcineurin in the mechanisms of antimalarial action of cyclosporin A, FK506, and rapamycin," <i>Biochem. Pharmacol.</i> , 48(3):495-503, 1994.
	C12 ✓	Bertrand <i>et al.</i> , "Sequential Administration of Camptothecin and Etoposide Circumvents the Antagonistic Cytotoxicity of Simultaneous Drug Administration in Slowly Growing Human Colon Carcinoma HT-29 Cells," <i>Eur. J. Cancer</i> , 28A(4-5):743-748, 1992.
	C13 ✓	Beutler <i>et al.</i> , "Racial variability in the UDP-glucuronosyltransferase 1 (UGT1A1) promoter: a balanced polymorphism for regulation of bilirubin metabolism," <i>PNAS USA</i> , 95(14):8170-8174, 1998.
SB	C14 ✓	Bhasker <i>et al.</i> , "Genetic polymorphism of UDP-glucuronosyltransferase 2B7 (UGT2B7) at amino acid 268: ethnic diversity of alleles and potential clinical significance," <i>Pharmacogenetics</i> , 10(8):679-685, 2000.

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SB	C15	Bible and Kaufmann, "Cytotoxic synergy between flavopiridol (NSSC 649890, L86-8275) and various antineoplastic agents: the importance of sequence of administration," <i>Cancer Res.</i> , 57:3375-3380, 1997.
	C16	Bible and Kaufmann, "Flavopiridol: a cytotoxic flavone that induces cell death in noncycling A549 human lung carcinoma cells," <i>Cancer Res.</i> , 56:4856-4861, 1996.
	C17	Bock <i>et al.</i> , In: Conjugation reactions in biotransformation, Elsevier, North Holland Biomedical Press, p. 357-364, 1978.
	C18	Boesch and Loor, "Extent and persistence of P-glycoprotein inhibition in multidrug-resistant P388 cells after exposure to resistance-modifying agents," <i>Anticancer Drugs</i> , 5(2):229-238, 1994.
	C19	Boesch <i>et al.</i> , "Restoration of daunomycin retention in multidrug-resistant P388 cells by submicromolar concentrations of SDZ PSC 833, a nonimmunosuppressive cyclosporin derivative," <i>Exp. Cell. Res.</i> , 196(1):26-32, 1991.
	C20	Boiteux-Antoine <i>et al.</i> , "Comparative induction of drug-metabolizing enzymes by hypolipidaemic compounds," <i>Gen-Pharmacol</i> , 20(4):407-412, 1989.
	C21	Bosma <i>et al.</i> , "Sequence of exons and the flanking regions of human bilirubin-UDP-glucuronosyltransferase gene complex and identification of a genetic mutation in a patient with Crigler-Najjar Syndrome, Type I," <i>Hepatology</i> , 15:941-947, 1992.
	C22	Bosma <i>et al.</i> , "The genetic basis of the reduced expression of bilirubin UDP-Glucuronosyltransferase 1 in Gilbert's Syndrome," <i>N. Eng. J. Med.</i> , 333:1171-1175, 1995.
	C23	Burchell and Coughtrie, "UDP-glucuronosyltransferases," <i>Pharmac. Ther.</i> , 43:261-289, 1989.
	C24	Burchell <i>et al.</i> , "The UDP Glucuronosyltransferase gene suprefamily: suggested nomenclature based on evolutionary divergence," <i>DNA cell biol.</i> , 10:487-494, 1991.
	C25	Burger <i>et al.</i> , "Pharmacokinetic interaction between rifampin and zidovudine," <i>Antimicrobial Agents and Chemotherapy</i> , 37(7):1426-1431, 1993.
	C26	Campain <i>et al.</i> , "Characterization of an unusual mutant of human melanoma cells resistant to anticancer drugs that inhibit topoisomerase II," <i>J. Cell Physiol.</i> , 155(2):414-425, 1993.
SB	C27	Carlson <i>et al.</i> , "Flavopiridol induces G <sup>1</sup> arrest with inhibition of cyclin-dependent kinase (CDK) 2 and CDK4 in human breast carcinoma cells," <i>Cancer Res.</i> , 56:2973-2978, 1996.

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Exam. Init.	Ref. Des.	Citation
SB	C28	Carrier <i>et al.</i> , "Isolation and characterization of the human UGT2B7 gene," <i>Biochem and Biophys. Res. Commun.</i> , 272:616-621, 2000.
	C29	Cascorbi <i>et al.</i> , "Frequency of single nucleotide polymorphisms in the p-glycoprotein drug transporter MDR1 gene in white subjects," <i>Clinic. Pharmacol Ther.</i> , 69:169-174, 2001.
	C30	Charuk <i>et al.</i> , "Interaction of Rat Kidney P-Glycoprotein with a Urinary Component and Various Drugs Including Cyclosporin A," <i>Am. J. Physiol.</i> , 266:F66-F75, 1994.
	C31	Chen <i>et al.</i> , "Fluorescence polarization in homogeneous nucleic acid analysis," <i>Genome Res.</i> , 9:492-498, 1999.
	C32	Chen <i>et al.</i> , "Calcium phosphate-mediated gene transfer: A highly efficient transfection system for stably transforming cells with plasmid DNA," <i>Biotechniques</i> , 6:632-638, 1988.
	C33	Cheng <i>et al.</i> , "Glucuronidation of catechol estrogens by expressed human UDP-glucuronosyltransferases (UGTs) 1A1, 1A3, and 2B7," <i>Toxicological Sciences</i> , 45:52-57, 1998.
	C34	Chien <i>et al.</i> , "In vitro evaluation of flavopiridol, a novel cell cycle inhibitor, in bladder cancer," <i>Cancer Chemother Pharmacol</i> , 44:81-87, 1999.
	C35	Chin <i>et al.</i> , "Reduced mRNA levels for multidrug-resistance genes in cAMP-dependent protein kinase mutant cell lines," <i>J. Cell Physiol.</i> , 152(1):87-94, 1992.
	C36	Clarke and Burchell, "The Uridine Diphosphate glucuronosyltransferase multigene family: function and regulation," <i>Handbook of experimental pharmacology</i> , 112:3-43, 1994.
	C37	Coffman <i>et al.</i> , "Cloning and stable expression of a cDNA encoding a rat liver UDP-Glucuronosyltransferase (UDP-Glucuronosyltransferase 1.1) that catalyzes the glucuronidation of opioids and bilirubin," <i>Mol. Pharmacol.</i> , 47:1101-1105, 1995.
	C38	Coffman <i>et al.</i> , "Human UGT2B7 catalyzes morphine glucuronidation," <i>Drug Metab Dispos.</i> , 25:1-4, 1997.
	C39	Coffman <i>et al.</i> , "The glucuronidation of opioids, other xenobiotics, and androgens by human UGT2B7Y(268) and UGT2B7H(268)," <i>Drug Metab Dispos.</i> , 26:73-77, 1998.
↓	C40	Cordon-Cardo <i>et al.</i> , "Expression of the multidrug resistant gene product (P-glycoprotein) in human normal and tumor tissues," <i>J. Histochem. Cytochem.</i> , 38:1277-1287, 1990.
SB	C41	Czech <i>et al.</i> , "Antitumoral activity of flavone L86-8275," <i>Int J Oncol</i> , 6:31-66, 1995.

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SB	C42	Davies and Schnell, "Oltipraz-induced amelioration of acetaminophen hepatotoxicity in hamsters," <i>Toxicology and Applied Pharmacology</i> , 109:29-40, 1991.
	C43	de Forni <i>et al.</i> , "Phase I and pharmacokinetic study of the camptothecin derivative irinotecan administered on a weekly schedule in cancer patients," <i>Cancer Res.</i> , 54:4347-4354, 1994.
	C44	De Lannoy <i>et al.</i> , "Cyclosporin and Quinidine Inhibition of Renal Digoxin Excretion: Evidence for Luminal Secretion of Digoxin," <i>Am. J. Physiol.</i> , 263:F613-F622, 1992.
	C45	De Morais <i>et al.</i> , "Biotransformation and Toxicity of Acetaminophen in Congenic RHA Rats with or without a Hereditary Deficiency in Bilirubin UDP-Glucuronosyltransferase," <i>Toxicology and Applied Pharmacology</i> , 117:81-87, 1992.
	C46	Decleves <i>et al.</i> , "A new polymorphism (N21D) in the exon 2 of the human MDR1 gene encoding the P-glycoprotein," <i>Human Mutation</i> , 15: 486, 2000.
	C47	Dhainaut <i>et al.</i> , "New Triazine Derivatives as Potent Modulators of Multidrug Resistance," <i>J. Med. Chem.</i> , 35:2481-2496, 1992.
	C48	Di Carlo <i>et al.</i> , "Flavonoids: old and new aspects of a class of natural therapeutic drugs," <i>Life Sci.</i> , 65:337-353, 1999.
	C49	Di Rienzo <i>et al.</i> , "Two new alleles in the promoter of the bilirubin UDP-glucuronosyl transferase 1 (UGT1A1) gene", <i>American Society for Clinical Pharmacology and Therapeutics</i> , Ninety Ninth Annual Meeting, New Orleans, Abstract OII-B-3, page 207, 1998.
	C50	Diasio <i>et al.</i> , "Clinical pharmacology of 5-fluorouracil," <i>Clin Pharmacokinet</i> , 16:215-237, 1989.
	C51	Dobbs and Twelves, "What is the effect of adjusting epirubicin doses for body surface area?" <i>British Journal of Cancer</i> , 78(5):662-666, 1998.
	C52	Doige <i>et al.</i> , "ATPase activity of partially purified P-glycoprotein from multidrug-resistant chinese hamster ovary cells," <i>Biochim. Biophys. Acta.</i> , 1109(2):149-160, 1992.
	C53	Drees <i>et al.</i> , "Flavopiridol (86-8275): selective antitumor activity in vitro and activity in vivo for prostate carcinoma cells," <i>Clin Cancer Res</i> , 3:273-279, 1997.
SB	C54	Egner <i>et al.</i> , "Regulation of Phase 2 Enzyme Induction by Oltipraz and other Dithiolethiones," <i>Carcinogenesis</i> , 15(2):177-181, 1994.

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SB	C55	Ewesuedo and Ratain, "Topoisomerase I inhibitors," <i>Oncologist</i> , 2(6):359-364, 1997.
	C56	Evans and Relling, "Automated high-performance liquid chromatographic assay for the determination of 7-ethoxycoumarin and umbelliferone," <i>J. Chromatogr.</i> , 578:141-145, 1992.
	C57	Ford <i>et al.</i> , "Cellular and biochemical characterization of thioxanthenes for reversal of multidrug resistance in human and murine cell lines," <i>Cancer Res.</i> , 50(6):1748-1756, 1990.
	C58	Fournel <i>et al.</i> , "Structure-dependent induction of bilirubin glucuronidation and lauric acid 12-hydroxylation by arylcarboxylic acids chemically related to clofibrate," <i>Biochimica et Biophysica Acta</i> , 842:202-213, 1985.
	C59	Foxwell <i>et al.</i> , "Identification of the multidrug resistance-related P-glycoprotein as a cyclosporine binding protein," <i>Mol. Pharmacol.</i> , 36:543-546, 1989.
	C60	Friche <i>et al.</i> , "In vitro circumvention of anthracycline-resistance in ehrlich ascites tumour by anthracycline analogues" <i>Biochem. Pharmacol.</i> , 39:1721-1726, 1990.
	C61	GenBank Accession Number AF297093.
	C62	GenBank Accession Number NM_001074.
	C63	Gestl <i>et al.</i> , "Expression of UGT2B7, a UDP-glucuronosyltransferase implicated in the metabolism of 4-hydroxyestrone and all-trans retinoic acid, in normal human breast parenchyma and in invasive and in Situ breast cancers," <i>American Journal of Pathology</i> , 160(4):1467-1479, 2002.
	C64	Gram <i>et al.</i> , "Clinical relevance of genetic polymorphisms in drug oxidation," <i>Clinical Relevance of Genetic Polymorphisms in Drug Oxidation</i> , 1992.
	C65	Green <i>et al.</i> , "Expressed human UGT1.4 protein catalyzes the formation of quaternary ammonium-linked glucuronides," <i>Drug Metab. Dispos.</i> , 23:299-302, 1995.
	C66	Grulic <i>et al.</i> , "Reversal of multidrug resistance by RU 486 <sup>1</sup> " <i>Cancer Res.</i> , 54(12):3088-3091, 1994.
	C67	Guillamette <i>et al.</i> , "Genetic polymorphisms in uridine diphospho-glucuronosyltransferase 1A1 and association with breast cancer among African Americans," <i>Cancer Res.</i> , 60:950-956, 2000.
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List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)	Applicant Mark J. Ratain <i>et al.</i>	
	Filing Date: January 5, 2004	Group: 1645
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>

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